

Plant Variety Protection Board Meeting Minutes
November 14 and 15, 2007
Room 1400
USDA National Agricultural Library (NAL) Building
10301 Baltimore Ave.
Beltsville, Maryland 20705

Board Members attending (with affiliation):

June Blalock; USDA, ARS, Office of Technology Transfer
Kelly Book; Texas Department of Agriculture
Kent Bradford; University of California, Davis
Steven Callistein; Pioneer Hi-Bred International, Inc.
Harry Collins; Delta and Pine Land Company
Carl Johnson; California Cooperative Rice Research Foundation, Inc.
Russell Karow; Oregon State University
Patrick Kole; Idaho Potato Commission
John Nelsen, RiceTec, Inc.
Bernice Slutsky; American Seed Trade Association
Larry Svajgr; Indiana Crop Improvement Association

USDA and AMS staff:

J. Burton Eller, Jr., Deputy Under Secretary for Marketing and Regulatory Programs (MRP)
Kenneth Clayton, Associate Administrator, USDA/Agricultural Marketing Service (AMS)
Robert Epstein, Deputy Administrator, USDA/AMS/Science and Technology
Alan Post, Associate Deputy Administrator, USDA/AMS/Science and Technology
Robert Ertman, USDA/Office of the General Counsel

Plant Variety Protection staff:

Robin Davis, Examiner
Sheila Littleton, PVP Analyst
James Mantooth, Examiner
Janice Strachan, Examiner
Jeff Strachan, Examiner
Bernadette Thomas, Information Technology Specialist
Beretha Thornton, Examiner
Leigh Wiltison, Associate PVP Examiner
Paul Zankowski, Commissioner

Visitors: Filipe Teixeira, EMBRAPA

Sign Language Interpreters

Opening remarks were made by Robert Epstein.

The meeting agenda was adopted. The Plant Variety Protection Board (Board) approved the minutes of the March 2007 meeting with a comment that the crop kind rape be identified as canola. It was indicated that the crop kind "rape" is the recognized kind by the Seed Regulatory and Testing Branch under the Federal Seed Act.

The Board had questions regarding the Appeal to the Secretary that was discussed at the March 2007 meeting. The Office of General Counsel (OGC) explained that the Board subcommittee did not hear the

Appeal since the Judicial Officer remanded the protest petition upon motion of the Commissioner because information developed during the appeal indicated that the variety might be eligible for protection. The variety initially was ruled to be ineligible for protection because the petition showed that 1) it had been sold to others for reproductive purposes more than one year before the application was filed and 2) the sales were not considered an integral part of a program of experimentation or testing to ascertain the characteristics of the variety.

The initial Commissioner's decision took into consideration the sale of plantlets to private growers who reproduce the variety for the evaluation of its growing and processing characteristics. It was ruled in the initial decision that unless results of these evaluations are reported back to the breeder, the sales are not an integral part of the breeder's program of experimentation or testing to ascertain the characteristics of the variety. However, in the applicant's final submission to the Secretary an affidavit from the manager of a tissue culture lab stated that growing results were reported back to the breeder each year at a meeting of researchers and growers who discuss the progress of new lines. The growers reported to the breeder on their experiences, their successes and failures with respect to experimental lines. It was decided that this is part of the decision making process in moving forward with a new, named variety.

In the remanded decision, the reporting from grower to breeder made the evaluation an integral part of the breeder's program to ascertain the characteristics of the variety and satisfied the provisions of Section 41 (b) (1) of the Plant Variety Protection Act (PVPA). This being the case, it was not necessary to consider whether the sale price of the plantlets represented cost-recovery or whether harvested material was used commercially. Accordingly, this protest was overruled and the examination of the PVP application will proceed.

The Board had questions on what types of information should be reported back to the breeder to satisfy the PVPA "new" provisions. OGC indicated that in barley, for example, if a brewer indicated that they liked a barley variety for making beer - this would not constitute information to the breeder, but rather marketing research. Whereas, if a brewer indicated that they liked a barley variety for making beer because it malted significantly better than their standard variety then this would be credible research information provided back to the breeding program.

The Board wanted to know if the PVP decision could be made public and that it is important for OGC to clarify what research information should be reported back to the breeder so that a variety meets the "new" criteria. OGC indicated that the Commissioner's decision letter could be provided to the Board and that the best approach for PVP applicants would be to file for PVP before any sales occur.

The Board wanted guidance from the PVPO on what information should be reported back to the breeder from these types of trials. OGC indicated that the problem with any guidance is that the "new" criteria is statutory not regulatory. The PVPO interprets the "new" criteria based upon the information provided in the PVP application, however the courts may interpret this information differently.

OGC indicated that it is important for any Material Transfer Agreement (MTA) to state that processors report trial and processing characteristics of a variety back to the breeder, thereby protecting the breeder's interest. The Board indicated that they would like to be informed whenever a decision of this type is made by the Commissioner. OGC indicated that this would be acceptable.

Discussions and Reports:

PVP, AMS, and USDA Information Technology, Douglas Bailey

Database presentation – The reasons to migrate from the PVPO's current non-standard STAR database to USDA's SQL standard include: 1) reducing the licensing and contractor support costs averaging \$37,000 annually, 2) eliminating the cryptic, complex query statements which often obscure third-party review of search criteria, and 3) leveraging the use of agency standard development tools to improve electronic business. Changing to a SQL database would improve database management / security; enhance business systems during migration to better meet informational and operational needs; and create a user environment that is easy to navigate and requires less user training and experience to use.

The first phase of the database conversion project was completed by a contractor for \$204,000 in 2004 to produce a Functional Design Requirements Specification Document, a System Alternatives Analysis Document (SAAD), and a Recommended Design Document. Phases 2-5, which were not completed, include 1) the conversion of all database tables and entry screens for each crop kind, 2) development of manuals and training, 3) maintenance, and 4) system enhancements. The Board had a question about the appropriation used for the first phase and why the money was no longer available (it was an appropriation that no longer exists). The Board also commented that the current STAR system has so many separate databases; in the new SQL system the STAR databases would exist as tables within a single SQL database. If the top 10-20 crops were migrated first, then two database systems would need to be run in parallel. The major cost for the database conversion is the user interface and maintaining PVP examiner functionality. The Board indicated that powerful proprietary software may exist that can fill the PVPO needs; they suggested the USDA broaden its search for acceptable software.

The PVPO needs to assure money exists to pay for this project and that a new database fulfills the cyber security requirement and improves efficiency. The database conversion would be done by a contractor, not USDA staff. The Board asked if other USDA offices have a similar database. It was explained that the functionality that the PVP data requires is very basic –and that data relationships are simple. The Board inquired if the crop data in the databases could be made public and if the public would help provide data to populate the crop databases. A PVP Examiner explained that in the past there was no strong interest from the public to synchronize their data with the PVP database.

The Board indicated that it was evident that the PVPO needs to change its database software and they wanted to know what action the Board should take. One proposal was that the PVPO establish a Capital fund using the \$750,000 surplus from FY2007 to modernize office functions and upgrade the database. If this proposal was endorsed the PVPO wanted to know how this fund should be financed. The Board questioned what alternatives the PVPO considered. The Board was asked to make a recommendation on how the PVPO does accounting for day-to-day operations and for long range programs such as the database conversion. It was mentioned that, in USDA programs, the major justification for fee increases is based on a shutdown analysis.

The Board had a general consensus that the database be upgraded, especially if enhancements can be extended to the users, but the Board wanted to know what are the options. The USDA can do a request for information for the conversion - if there is a solid plan to fund the database conversion. The Board wanted to know more about the funding options. The PVPO money is currently in one fund with a balance over \$2 million. The PVP money would then exist in a trust fund and a capital improvement fund that would support the day-to-operations and long term capital improvements, respectively. The Board was worried that user fees could still not support and fully finance both of these funds. If a fee increase was needed in the future then moving money out of the trust fund into the capital fund would

increase the likelihood of required fee increase docket with endorsement by USDA's Office of Budget and Program Analysis and approval by the Office of Management and Budget (OMB).

The Board wanted to know if it recommends that \$750,000 be locked into a capital fund how would a potential fee increase be split - between the trust and the capital funds. The PVPO indicated that the trust fund is financially secure with \$2.3 million in the fund; the office wants to move \$750,000 to the new capital fund. There appeared to a general consensus that the PVPO establish the Capital fund to finance the database conversion, but no motion was put forward by the Board.

A presentation was made on the use of electronic forms. The PVPO will create fillable pdf forms for the top five "Objective Description of Variety" forms by May 2008 (e.g., Corn and Soybean). These forms can be completed off-line and emailed to PVPO for electronic submission. The users of e-forms would phone/email the PVPO to indicate that an electronic form and payment would be arriving at the PVPO. An issue that needs to be resolved involves the National Archives and Records Administration (NARA) requirements for record retention with e-forms. It was discussed that filling a form offline and emailing would be more practical than filling a form online in one session. Offline form filling would eliminate the need for the USDA to store proprietary information on a server for forms that are partially filled and not filed. The PVPO will evaluate the cost and benefits of supporting of the completion and submission of electronic forms for manual "back-office" processing versus electronic "back-office" processing.

Since payment information submitted by applicants is proprietary the online processing of PVP payments (and subsequently applications) will require electronic credentials. The USDA's e-Authentication service is the single solution used by USDA to conduct electronic business with customers in an authoritative and non-refutable manner. Individuals must register and prove their identity to USDA to receive a credential for conducting business (a Level 2 credential). Generic company credentials that require only a valid email address can also be established, but because the identity of the user is not known authoritatively, these can only be used for accessing personalized web pages (a Level 1 credential). A Board member commented that APHIS has set up a booth to e-authenticate for level 2 at ASTA meetings.

Currently the PVPO accepts credit card payments using faxed information. The PVPO is working with the AMS Information Technology Group to develop an electronic payment system integrating pay.gov with the PVPO application forms. Applicants would use Level 2 credentials to access the payment site and enter credit card information electronically through a secure connection.

The PVPO website enhancements were discussed which would improve the certificate search capabilities. More PVP database search options will be added so that in addition to Variety Name, Certificate number, and Owner, the public can search by: Kind, Application Status, Certified seed option, Application date, and Issuance date. Users will be able to download the results of their query to Excel or other file formats. The Board commented that the public searching and downloading of information features are very useful to users.

By spring 2008, the AMS Internet web site, including the PVPO pages, will have a new look and page organization. This change is intended to make content easier for new users to find and provide a consistent look and navigation framework for all USDA websites. Browser bookmarks will need to be reset on first-time use. Outside contractors have designed the website layout, but branch webmasters fill in the content.

Working Capital Fund and the PVPO Financial Update - Robert Epstein and Melissa Tharp

Within the Agricultural Marketing Service a working capital fund (WCF) fulfills the long-term capital needs (i.e., assets with acquisition costs above \$25,000 (\$100,000 for software) and a useful life of at least 24 months) from capital resources; funds are reimbursed to the WCF through depreciation charges. The major players in USDA's decision-making process for WCF includes 1) the CFO – Chief Financial Officer – is the responsible official for the WCF ensuring its financial health and serves as the Chairperson for the WCF Executive Committee; 2) the ASA – Assistant Secretary for Administration – serves as the Vice-Chairperson for the WCF Executive Committee and works on improving performance and services; 3) the WCF Executive Committee – high level senior management group established to provide the CFO with advice and counsel with regard to the management of the WCF; and 4) the WCF Work Group – reports to the WCF Executive Committee includes the WCF Controller, representatives from each mission area, and the Department's Budget Office. (This group conducts in-depth analyses of policy and annual budget proposals for the various initiatives.).

The PVPO's top ranked expenses are: Salaries and Benefits (76.96%), Utilities (9.14%), Contractual Services (5.98%) Departmental Assessment (=overhead, 3.28%), Equipment (1.52%), and Others (3.12%). The PVPO's Greenbook departmental assessment is 0.35% of the agency's costs.

The last PVPO fee increase occurred in October 2005 and was an 18.8% increase above the previous fees. Currently a total of \$5,150 in fees is collected for each issued PVP certificate which gives 20 years of intellectual property protection from the issuance date for most crops other than trees and vines.

In FY2007 total obligations were \$1,706,084 and revenue was \$2,497,019. The PVPO received \$24,335 in appropriated funds for international work during FY2007. The trust fund balance at the end of FY2007 was \$2,318,055. The total of all obligations for the PVPO in FY2008 is \$1,986,080 including Science & Technology and AMS overhead. Revenue for FY2008 is estimated to be \$1,900,000 based on 350 incoming PVP application and would result in an \$86,000 deficit to the trust fund.

The Board wanted to know if a "what-if" analysis could be performed so the Board can evaluate the effect of reduced incoming PVP applications, increased obligations, etc. The Board asked if the PVPO queries customers about future PVP applications to assist the PVPO in budgeting revenue. A Board member commented that it is difficult to predict which varieties should file for PVP until the variety is ready to sell. The Board commented on the high number of PVP applications (455) received in FY2007 and wanted to know if this trend would continue. Board members said that companies are releasing varieties quicker and they don't foresee a reduction in PVP filing. The PVPO wanted to know how to plan for an increasing number of incoming applications – should more staff be hired and should a capital fund be created.

The Board commented that assessing these trends was a part of strategic planning and this Board cannot manage the PVPO's operation; they indicated that the PVPO needs to make the proposals and decide what action to take. A Board member commented that the PVPO should focus on the benefits side of Plant Variety Protection with regards to the harmonization of filing for plant breeder's rights internationally. It was indicated that PVP is better recognized internationally than patents and that seed companies want PVP if they are trying to sell seed internationally.

A Board member commented that the PVPO may need to look at rebalancing its fees such that the certificate fee is higher than the application fee; thereby reducing the upfront cost, which might be an incentive for more applications. Another Board member commented that the current fee structure is

better with a higher front end fee; otherwise with a higher certificate fee the PVPO might experience more abandonments after finishing all the database search work.

It appeared that the Board had a consensus to modernize the database, but the money would not come from an outside source. The AMS budget officer indicated that a PVPO capital fund can be created; but the Office of General Counsel (OGC) has indicated that the PVPO cannot charge a separate IT capital fee to finance this fund.

The Board asked when the database conversion project could be started and they were told it could be planned within 6 months. If a database bid is made by a contractor, then it would be important to have all the money available to obligate for the project. If the project was only partially funded, then 2 database systems may need to operate in parallel. It was estimated that the conversion to a usable product could be completed by 2011. The Board asked if the PVPO could borrow money from the USDA or if there was a way to accept grants from the seed industry. OGC indicated that the PVPO cannot accept grants or gifts from anyone, including seed trade organizations.

The Board wanted to know if the PVPO would need to begin the database project from scratch or if it could continue with the unfinished phases of the project. It was explained that a request for information (RFI) would specify a contractor to focus on the Phases 2-5 of the conversion project. The Board indicated that they would like to better explain the database situation and the need for funding to their constituents, but it was not possible based on the current information. Any fee increase could be contingent on an RFI and that the amount of the increase can be linked to the resulting bids.

The Board suggested that any electronic application filing system and database conversion focus on the routine crops not the low volume specialty crops. Lastly the Board was worried about borrowing \$750,000 from the PVP Trust fund and how low the trust fund balance might drop.

PVPO E-business Update - Bernadette Thomas

The strategy and the justification for the database migration from STAR to SQL was presented. Other updates were given on 1) developments in obtaining electronic signatures using the USDA e-authentication process, 2) the progress on the design of e-filing systems, 3) status of the PVP online payment system, 4) current structure and proposed changes to the PVP website, and 5) current security and disaster recovery IT systems for the PVPO.

Day 2 - Thursday, November 15, 2007

J. Burton Eller, Jr. and Kenneth Clayton welcomed the Board members and thanked them for their diligence. The Board stressed the importance of the PVPO to international agriculture and that the PVPO needs the vision and strategic plan to think and interact globally. The Board emphasized that the PVPO needs to receive appropriated funds because of its international obligations that are not connected to PVP application review and user fees. The Board was told that the PVPO received international standards appropriation funds to carry out some international work; however there has been no increase in this funding yet and an increase in international funding would be justified because of the international work. The Board said that the industry would like to help updating the PVP database systems. The Board indicated that fee increases may have a negative impact on the PVPO especially if application fees are more than \$6000.

The Board highlighted the international importance of the PVPO; more involvement in UPOV, and how the US PVPO speed obtaining foreign plant breeder's rights. Mr. Eller commented that it is important for the Board to see the PVP strategic and business plans, the Board minutes are important, and the Board is free to make business and strategic plan recommendations. The Board commented that specific recommendations were made at the last meeting and that the PVPO's international and bilateral work continues to be very important. Mr. Eller indicated that someone from the Board or PVPO should make a report to the administrator and the Undersecretary; perhaps the Board should have a chairman to report on this meeting.

Topics brought forward by Board members - Paul Zankowski.

Four topics were brought forward including 1) the UPOV Train the Trainer course that is scheduled at U.S. Patent and Trademark Office (PTO) in Alexandria, Virginia for February 25-29, 2008; 2) the ISF presentation to UPOV on experiences and initiatives for the development of electronic application forms; 3) the UPOV and the National Council of Commercial Plant Breeders (NCCPB) definitions of terms used to describe variety response; and 4) the use of molecular markers in combination with other genetic differences to distinguish a proposed variety.

The Board was provided with application forms for the UPOV Train the Trainer course. The focus of the course is to provide training for individuals ("trainers") who will provide training on plant breeders' rights under the UPOV Convention.

The International Seed Federation (ISF) made a presentation at the fall UPOV meeting on how UPOV members could harmonize to allow a common form for filing PVP among many UPOV member states. The Board commented that the harmonization of forms with other UPOV members is a clear example how the US PVPO can provide a benefit. The Board also commented that the UPOV forms/technical guidelines system doesn't gather practical information and that some UPOV traits are informative, but others such as color and leaf size may not be informative. Some Board members stressed that they would like more quantitative traits and molecular data used for UPOV/PVP forms. The Board indicated that PVPO representatives should meet with stakeholders to discuss the harmonization of forms and that this type of international work is a good justification for PVPO getting appropriated funds.

A Board member indicated that UPOV proposed removing the term "Tolerance" regarding variety response during the spring 2007 meeting in the UPOV document TGP/12/1 Draft 1. It was suggested that the US delegation to UPOV make note of this situation and that it should not approve of any papers that are missing the "tolerance" designation. A Board motion was made and unanimously carried that the US delegate to UPOV ask that the term "tolerance" be allowed for biotic and abiotic factors and that "tolerance" as a character state (separate from the terms resistance and immunity) be reinstated by UPOV.

The Board discussed the use of molecular markers with regard to the circumstance when a single base pair DNA difference between two varieties would render the varieties as distinct. The Board asked about the UPOV discussion on the use of molecular marker technology and language that distinctness should not be associated with non-expressed DNA. OGC indicated that the U.S. did not need to subscribe to the UPOV guidelines when it signed the convention. OGC referred to the Definitions and Rules of Construction of the PVPA, specifically section 41 (b) part 5.

(5) DISTINCTNESS.- The distinctness of one variety from another may be based on one or more identifiable morphological, physiological, or other characteristics (including any characteristics evidenced by processing or product characteristics, such as milling and baking characteristics in the case of wheat) with respect to which a difference in genealogy may contribute evidence.

OGC indicated that the “other characteristics” can be based on DNA – if a single DNA base pair can be readily distinguished – the variety is different.

PVP Strategic Plan, Janice Strachan

The PVPO’s 2007-2012 Strategic plan was presented. Approximately 325 new applications should come to the PVPO in FY2008 based on averaging previous trends. The PVPO has decreased the processing time for incoming applications to below 35 months. The PVPO has seen an increasing number of incoming applications using biomolecular data in support of the distinctness claims.

The draft strategic plan provided 3 goals for the PVPO:

1. Optimize PVP Certificate Quality and Timeliness by
 - providing high quality examination of applications
 - improving and integrating the existing electronic systems to promote full electronic application processing; implement better more secure systems
 - improving the quality and timeliness of examinations by exploring a range of approaches to examining applications
 - developing interactive on-line electronic filing capabilities and upgrade e-tools and providing electronic file management and workflow
2. Achieve Organizational Excellence by
 - functioning as true business partners across the organization to achieve superior enterprise performance and provide strategic leadership
 - ensuring operational excellence in enterprise-wide management processes
 - dramatically simplifying on-line access to, and availability of, PVP Office information and data
3. Improve Plant Breeder’s Rights and Enforcement Domestically and Abroad by
 - supporting the efforts and initiatives aimed at strengthening IP Protection and curbing theft of IP
 - continuing efforts to develop unified standards for international IP practice
 - providing the policy guidance on domestic IP issues
 - fostering innovation and competitiveness by delivering IP information and education worldwide

The Board commented that the plan had tactical and strategic components. It was suggested that a conference call be scheduled in the future for the Board to further discuss the details of the strategic plan. It was proposed that a subcommittee of the Board get organized regarding the details of the strategic plan.

The PVPO will setup a Sharepoint website where the Board members can review and revise documents, setup subcommittee meetings, and better communicate with each other. When final versions of Board documents are developed – they will be posted on the PVPO public website.

The Board asked if the area of grants to the PVPO could be revisited and verified. The Board wanted the PVPO to develop its dream list and problem list. It was suggested that three Board subcommittees be formed – one to evaluate the strategic plan, another to look at the PVPO financial issues, and a third to look at possible alternatives.

The Board suggested that a letter from the Board to the Secretary be prepared on appropriation funding for the PVPO; however the Board will need specifics on what needs to be funded. It was also recommended that these reports be sent to the Secretary and the MRP Undersecretary and Deputy

Undersecretary. The Board suggested that representatives of the Board meet with the Chief of Staff for the Secretary as coordinated by ASTA. It was also recommended that the PVPO supply the Board minutes to the Undersecretary's office along with any follow-up on the strategic plan. The Board said that a fair amount of thought be put into the construction of the letter regarding the value of intellectual property rights to America.

The Board had concerns regarding the subcommittee meeting and how not to violate the Federal Advisory Committee Act; OGC indicated that since it was currently being discussed in public – that it would not interfere. It was proposed that a subset of the Board request a meeting with the Chief of Staff and Undersecretary and that this group hand delivers the Board letter. The Board wanted the PVPO to prepare a bulleted list of what is needed for the database system.

A motion was put forward that the Board members Patrick Kole, Bernice Slutsky, Russell Karow, and Steve Callestein draft the document, and soon thereafter meet with the Undersecretary. The motion was carried. It was suggested that the document be expanded to indicate that the PVPO serves not only the seed industry, but also the farm community and ultimately the consumers. It was suggested that the importance of the PVPO be promoted to the Farm Bureau. The plan was to have the first draft of this letter go to the PVPO and then to the Board.

The Board suggested that the PVPO write the detailed proposal for funding - so that when money becomes available the PVPO is ready. The Board indicated that it doesn't want to put its credibility on the line without a good proposal ready. It was discussed that perhaps the Board doesn't need to hand a letter to the Undersecretary about the funding, but rather what priorities the Board thinks are important – the PVPO has the responsibility on the database side of what is necessary.

The Board highlighted the areas that the PVPO financial analysis needs to focus: 1) money for the database conversion; 2) money for international meeting attendance, and 3) either money for additional clerical support or automation (the examiners wasted time on data entry should be detailed).

A Board subcommittee will draft the letter and create bullet points highlighting the PVPO's needs; however, they will not meet with the Undersecretary until they have more information from the PVPO.

The Board was provided with a handout of the PVPO Accomplishment presentation and the PVPO 2008 Business Plan. Neither of these was discussed in detail.

For old business the Board suggested that the PVPO check on the status of Board Recommendation number 4 from the March 2007 meeting. This recommended that a letter be drafted by the Secretary to the House Judiciary Committee regarding the Federal Circuit decision and the analogies between the Plant Variety Protection Act (PVPA) to Patent Law.

It was suggested that the next Board meeting take place via conference call in spring 2008 and / or an on site meeting for fall 2008.

Board Recommendations/Motions

1. The US delegate to UPOV ask that the term “tolerance” be allowed for biotic and abiotic factors and that “tolerance” as a character state (separate from the terms resistance and immunity) be reinstated by UPOV.

2. Board members Patrick Kole, Bernice Slutsky, Russell Karrow, and Steve Callestein will draft a document from the Board to the Secretary on appropriation funding, and soon thereafter meet with the Undersecretary.

Meeting adjourned.